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| | 08/821,02 | 5 03/19/ | 97 BIJL | | Н | 246152006900 | |
| Г | | | HM12/1 | 203 7 | | EXAMINER | |
| | SHMUEL LIVNAT MORRISON AND FOERSTER | | | 200 | MARX,I | | |
| | | | | | ART UNIT | PAPER NUMBER | |
| | 2000 PENNSYLVANIA A WASHINGTON DC 20006 | | | | 1651 | 19 | |
| | | | | | DATE MAILED: | 12/02/99 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No. 08/821,025

Applicant(s)

Bijl et al.

Examiner

Irene Marx

Group Art Unit 1651



| X Responsive to communication(s) filed on Oct 25, 1999 | | | |
|---|---|--|--|
| ☐ This action is FINAL . | | | |
| ☐ Since this application is in condition for allowance except for formal in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. | | | |
| A shortened statutory period for response to this action is set to expire is longer, from the mailing date of this communication. Failure to respapplication to become abandoned. (35 U.S.C. § 133). Extensions of 37 CFR 1.136(a). | ond within the period for response will cause the | | |
| Disposition of Claims | | | |
| X Claim(s) 1-31 and 33-36 | is/are pending in the application. | | |
| Of the above, claim(s) <u>1-26 and 34-36</u> | is/are withdrawn from consideration. | | |
| Claim(s) | is/are allowed. | | |
| | | | |
| Claim(s) | is/are objected to. | | |
| Claimsa | are subject to restriction or election requirement. | | |
| Application Papers | | | |
| ☐ See the attached Notice of Draftsperson's Patent Drawing Review | ew, PTO-948. | | |
| ☐ The drawing(s) filed on is/are objected to b | by the Examiner. | | |
| ☐ The proposed drawing correction, filed on | is 🗀 approved 🗔 disapproved. | | |
| The specification is objected to by the Examiner. | | | |
| $\hfill\Box$ The oath or declaration is objected to by the Examiner. | | | |
| Priority under 35 U.S.C. § 119 | | | |
| ☐ Acknowledgement is made of a claim for foreign priority under | 35 U.S.C. § 119(a)-(d). | | |
| ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the pr | riority documents have been | | |
| received. | | | |
| ☐ received in Application No. (Series Code/Serial Number) _ | | | |
| ☐ received in this national stage application from the International | | | |
| *Certified copies not received: Acknowledgement is made of a claim for domestic priority unde | | | |
| Acknowledgement is made of a claim for domestic priority unde | 91 35 U.S.C. § 119(e). | | |
| Attachment(s) | | | |
| Notice of References Cited, PTO-892 ☐ Information Displayure Statement(s), PTO 1449, Pages No(s) | | | |
| Information Disclosure Statement(s), PTO-1449, Paper No(s).Interview Summary, PTO-413 | | | |
| ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 | | | |
| ☐ Notice of Informal Patent Application, PTO-152 | | | |
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| | | | |
| SEE OFFICE ACTION ON THE FO | LLOWING PAGES | | |

Since this application is eligible as a Continued Prosecution Application under 37 CFR 1.153(d), the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.153(b). Applicant's submission after final filed on 10/25/99 has been entered.

Claims 27-31 and 33 are being examined on the merits. Claims 1-26 and 34-36 are withdrawn from consideration as directed to a non-elected invention.

Applicants arguments regarding basis and support for dead cells are persuasive, since claim 27 may be interpreted as consisting essentially of cells that have been pasteurized and treated further to prevent out-growth, as disclosed at page 11, lines 9-22 of the Specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-31 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the use of the phrase "the extrudate having a structure that allows a solvent access, via the pores, to the dead cells...", and the phrase "in order to isolate or extract a desired compound therefrom". It is unclear how it is assured that the access is necessarily "via the pores", It is further unclear which compounds are "desired" and how they are isolated or extracted in this context, particularly since there does not seems to be a clearly defined correlation between the type of fungus, the nature of the solvent and/or the class of compound to be isolated.

Claim 33 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend on another multiple dependent claim. See MPEP § 608.01(n). However, the claim has been treated on the merits to the extent that it is understood.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-31 and 33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huang *et al.* or Cockram *et al.*.

The claims are drawn to a granular fungal composition which has been dried and extruded.

Each of the cited reference discloses a granular fungal composition which has been dried and extruded which appears to be identical to the presently claimed composition (see, e.g., Example 1; col. 3, line 35 et seq.) since it is granular, dried and extruded and appears to be porous and to allow, via the pores, access to a solvent to the dead cells to isolate or extract a desired compound therefrom. The referenced composition also appears to be free-flowing at least to some extent. The referenced composition appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it is of the same class as that of the composition claimed and is taught to have the same properties of being a granular,

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extruded, dried and dead fungal composition suitable for similar purposes. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, such as the size of the granular particles, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share. Thus the claimed composition would have been obvious to those skilled in the art within the meaning of USC 103.

Furthermore, the composition of claims 27-31 and 33 is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Accordingly, the claimed invention as a whole was at least <u>prima facie</u> obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 28-31 and 33 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rhodes *et al.*.

The claims are drawn to a granular fungal composition which has been dried and extruded.

Rhodes et al. disclose fungal biomass which comprises dried, extruded granules. See e.g., Examples. From Table III it can be presumed that the average dry matter content is at least 30% and can be greater than 80%. The dried granular fungal composition appears to be identical to the presently claimed composition since it is granular, dried and extruded and appears to be porous and to allow, via the pores, access to a solvent to the dead cells to isolate or extract a desired compound therefrom. The referenced composition also appears to be free-flowing at least to some extent. The referenced composition appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it is of the same class

as that of the composition claimed and is taught to have the same properties of being a granular, extruded, dried and it is presumed that at least some of the fungal composition comprises dead cells. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, such as the size of the granular particles, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share. Thus the claimed composition would have been obvious to those skilled in the art within the meaning of USC 103.

Furthermore, the composition of claims 28-31 and 33 is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Accordingly, the claimed invention as a whole was at least <u>prima facie</u> obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Applicants' arguments have been fully considered but they are not deemed to be persuasive.

In response to applicants' arguments that the dried, extruded granules of Rhodes are "required to live in order to sporulate and then kill insects", it must be remembered that the claimed composition is claimed in terms of the open language "comprises". Therefore live cells are not excluded. Moreover, the dried, extruded granules of Rhodes are reasonably likely to comprise at least a few dead fungal cells therein.

Therefore the rejection is deemed proper and it is adhered to.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Irene Marx

Primary Examiner

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